Before the
FOOD AND DRUG ADMINISTRATION
Rockville, MD 20852

In re: Written Comments in Response to Announcement of Public Meeting on "How to Use Health Claims and Nutrient Content Claims in Food Labeling; Public Meeting," 64 FR 14178	)	**Docket No. 99N-0554**

COMMENTS OF AMERICAN PREVENTIVE MEDICAL ASSOCIATION; PURE ENCAPSULATIONS, INC.; WEIDER NUTRITION INTERNATIONAL, INC.; and JULIAN M. WHITAKER, M.D.

The American Preventive Medical Association ("APMA"); Pure Encapsulations, Inc. ("Pure"); Weider Nutrition International, Inc. ("Weider"); and Julian M. Whitaker, M.D. ("Dr. Whitaker") (collectively, the "Joint Commenters") hereby submit their comments in response to the agency's request for comments in the above-referenced docket.

In the Announcement of Public Meeting published in the March 24, 1999 Federal Register, 64 Fed. Reg. 14178 (March 24, 1999), the agency submits a series of questions and asks the public to comment on its queries, presumably to guide the agency in determining how it will revise nine interim final rules published in the June 22, 1998 Federal Register, 63 Fed Reg 34084-34115. The Joint Commenters have objected to those rules on statutory and constitutional grounds in comments filed in response to them and welcomes the opportunity to advise the agency on ways to interpret the statute that will satisfy the requirements of Section 303 of the Food and Drug Administration Modernization Act, the Administrative Procedure Act, and the First Amendment to the United States Constitution.

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Conspicuously absent from the agency's queries is a question concerning the effect of *Pearson v. Shalala*, 164 F.3d 650 (D.C. Cir. 1999), *reh'g denied,* 1999 U.S. App. Lexis 5954, on the nine Interim Final Rules. In pertinent part, *Pearson v. Shalala* stands for the proposition that FDA may not suppress potentially—as opposed to inherently—misleading commercial speech, including health claims, but must authorize the claims with reasonable disclaimers designed to eliminate the perceived potential to mislead. Disclosure over suppression is a constitutional imperative that FDA may not ignore.

Moreover, *Pearson* stands for the proposition that health claims that are not approved under FDA's "significant scientific agreement" standard must nevertheless be permitted by FDA when accompanied by a reasonable disclaimer designed by the agency to cure "misleadingness," the term coined by the Court. Applying *Pearson* to the nine Interim Final Rules yields the ineluctable conclusion that FDA may not prohibit any claim accurately representing an authoritative statement (even ones FDA holds insufficient under FDAMA Section 303) but must permit every such claim, relying on reasonable disclaimers in lieu of suppression as its method of avoiding misleadingness. In short, instead of suppression *Pearson* mandates disclosure with reasonable disclaimers.

Below, the Joint Commenters answer each of the questions posed by the agency, seriatim.

1. The Scientific Basis for Claims

a. What is an "authoritative statement"?

At the very end of Sections 403 (r)(2)(G) and (r)(3)(C), 21 U.S.C. § 343(r)(2)(G);(r)(3)(C), the statute unambiguously defines "authoritative statement:"

> For purposes of this clause, a statement shall be regarded as an authoritative statement of a scientific body described in subclause (i) only if the statement is published by the scientific body and shall not include a statement of an employee of the scientific body made in the individual capacity of the employee.

Under the statute a statement "shall be regarded" (as opposed to "may be regarded" or "can be regarded") as "authoritative" if it is published by a scientific body and is not a statement of an employee of the scientific body made in that employee's individual capacity. Had Congress intended to define the term differently or to impose other conditions, akin to the numerous conditions contained in the Interim Final Rules, it would have done so in this clause. Or, it would have invited FDA to do so, as it did in the case of the "significant scientific agreement" standard. Congress did neither. Congress has spoken simply but clearly. Consequently, "that is the end of the matter; for the court, as well as the agency, must give effect to the unambiguously expressed intent of Congress." *Chevron USA, Inc. v. Natural Resources Defense Council, Inc.*, 467 U.S. 837, 842-3 (1984).

The Senate and House Reports reveal that Congress intended FDAMA Section 303 to serve as an expeditious alternative to the "significant scientific agreement" standard, not a redundancy. Congress reacted adversely to FDA's refusal to authorize a folic acid/neural tube defect claim under the "significant scientific agreement" standard for a period of three and one-half years, during which time approximately 2,500 preventable neural tube defect births occurred each year. Congress sought to prevent recurrence of that kind of speech suppression and harm to public health by creating an expeditious alternative to significant scientific agreement, one that would enable consumers to receive health and nutrient content claims if those claims were accurate representations of statements published by scientific bodies of the United States having

official responsibility for public health protection or research directly relating to human nutrition. Congress clearly rejected as untenable and, indeed, damaging to public health (witness congressional discussion of the case of the folic acid claim), any requirements that petitioners prove to FDA's satisfaction the intrinsic validity of scientific publications by U.S. scientific bodies. Rather, Congress entertained no discussion of the need for proof to FDA's satisfaction but accepted statements published by other federal government health agencies to be the routine product of scientific analysis (without provision for, or need of, FDA second-guessing).

b. Who defines "authoritative statement"?

Congress has defined the term in the statute. In the absence of definitional ambiguity, FDA has one duty: to implement the statutory definition faithfully. There is no room for the imposition of additional qualifications on that statutory definition, particularly in light of the clear mandate of Congress that FDAMA Section 303 serve as a streamlined alternative procedure to FDA deliberative review under "significant scientific agreement." FDA should not attempt to undermine Congress's purpose by imposing definitional strictures that require a degree and level of proof approximating that required for "significant scientific agreement" when Congress chose not to mimic, but to provide a meaningful alternative to, that standard.

c. Who decides if a particular statement is an "authoritative statement"?

Under the statute, the test is a simple one of fact. The FDA must ascertain whether the statement is published by a scientific body of the United States government or is instead the statement of an employee of the scientific body made in that employee's individual capacity. If the former, the statement is authoritative; if the latter, it is not.

The statute provides no basis for FDA to impose additional regulatory strictures or to pose queries to other agencies as a litmus test for authorization.

The statute defines scientific bodies of the United States as those having "official responsibility for public health protection or research directly relating to human nutrition (such as the National Institutes of Health or the Centers for Disease Control and Prevention) or the National Academy of Sciences or any of its subdivisions." 21 U.S.C. § 343(r)(3)(C)(i). Thus, upon receipt of information establishing that the statement in question was published by a scientific body of the United States and that the statement is not one of an employee of that body acting in his or her individual capacity, the agency's inquiry is over: the statement is "authoritative" within the meaning of the statute.

d. Is the "context" of a statement in the publication in which it appears relevant to that determination? If so, how?

Context is not relevant to a determination of whether a statement is "authoritative" within the meaning of the statute. The definition given by Congress does not call for or invite a qualitative evaluation.

Context is relevant to determine whether the claim derived from the authoritative statement is an "accurate representation" of a published statement within the meaning of 21 U.S.C. §§ 343(r)(2)(G)(iv); 343(r)(3)(C)(iv).

e. How does the significant scientific agreement standard apply to health claims based on authoritative statements?

The system for claims review under FDAMA Section 303 is intended to be a streamlined alternative to "significant scientific agreement." The legislative intent underlying FDAMA Section 303 identifies only one specific kind of circumstance in which Section 303 may not be used as an alternative to "significant scientific agreement"

claims review. The only mention of the use of significant scientific agreement review is in the context of instances in which a claim that FDA has approved pursuant to 21 U.S.C. § 343(r)(3)(B) addresses the same subject as a claim based on an authoritative statement. In that instance, the congressional history explains that FDA may rely on its significant scientific agreement review procedure. To construe this limited exception to be a rule of general applicability for all notifications filed under FDAMA Section 303 violates the general intention of Congress, that FDAMA Section 303 serve as a meaningful streamlined alternative to "significant scientific agreement."

2. Existing Regulatory Requirements

a. What requirements of 21 C.F.R. § 101.13 and part 101, subpart D should we apply to nutrient content claims based on authoritative statements?

None of the requirements of 21 C.F.R. § 101.13 and part 101, subpart D, should be made applicable to nutrient content claims based on authoritative statements, because those claims are an exception to the pre-existing regime, meant to be governed instead by the statutory procedure established in 21 U.S.C. § 323(r)(2)(G).

b. What requirements of 21 C.F.R. § 101.14 should we apply to health Claims based on authoritative statements?

None of the requirements of 21 C.F.R. § 101.14 should be made applicable to health claims based on authoritative statements, because those claims are an exception to the pre-existing regime, meant to be governed instead by the statutory procedure established in 21 U.S.C. § 323(r)(3)(C).

2. Procedural and Definitional Issues

a. Which agencies should we identify as scientific bodies of the U.S. Government with official responsibility for public health protection or

research directly relating to human nutrition under Section 403(r)(2)(G)(i) and (r)(3)(C)(i) of the act?

FDA should refrain from creating any master list of such agencies because that would circumscribe the plain meaning of the terms "public health protection" and "research directly relating to human nutrition" and would cause the statutory provision to be rendered anachronistic over time. Instead, FDA should accept that Congress may from time to time ascribe to any agency of the federal government it thinks fit a scientific mission that involves public health protection or research directly relating to human nutrition (which may not now be among the agencies so empowered by Congress). Thus, FDA should on a case by case basis examine whether the agency of the federal government relied upon for an authoritative statement by a petitioner is one that has a legal mission that includes public health protection or the performance of research directly relating to human nutrition. That approach will ensure that the statutory provision is interpreted in a principled manner and is not rendered anachronistic with the passage of time.

b. Should we provide by regulation that health claims based on authoritative statements may be used in the labeling of dietary supplements?

Congress plainly contemplated use of Section 303 claims on dietary supplements because its primary motivation for the new section lies in FDA's suppression of a folic acid/neural tube defect claim. Folic acid, although contained within foods, is itself a dietary ingredient. Congress discussed folic acid, the ingredient, and did not limit its focus to folic acid-containing foods. Folic acid in and of itself is a dietary supplement when so labeled in conformity with supplement labeling requirements. The agency's

rules on folic acid claims known to Congress when it reviewed the matter pertained not only to foods in common form but also to dietary supplements. Thus, it is completely consistent with legislative intent for the agency to permit use of FDAMA Section 303 on foods and on dietary supplements. Moreover, there is nothing in FDAMA Section 303 that would prohibit the application. Finally, a failure to apply the rule uniformly to foods and dietary supplements would be an arbitrary and capricious action, one not based on a justifiable distinguishing principle.

c. What should we require that you submit with a notification of a health or nutrient content claim based on an authoritative statement?

FDA should be mindful of the fact that Congress intended FDAMA Section 303 to provide a streamlined alternative to "significant scientific agreement." The need for rapidity and ease of approval were regarded by Congress as central reasons for rejecting the agency's pre-existing claims review process in favor of a new method for claims based on authoritative statements. Indeed, Congress sought to avoid the high costs and lengthy delays associated with petitions for health claims approval under the "significant scientific agreement" review regime. In that regard, Congress provided necessary and sufficient review procedures in the statute. Accordingly, to fulfill the will of Congress FDA must avoid imposing any requirements on petitioners beyond specified in the statute. The statute contemplates the submission of only three material items. FDA should not add to the list. Congress expects that claimants will file a notice of the claim, which shall include the exact words used in the claim and shall include a concise description of the basis upon which such person relied for determining that the" statement is published by a scientific body of the United States, is currently in effect, and—in the case of a nutrient content claim—identifies the nutrient level to which the claim refers

or—in the case of a health claim—identifies the relationship between a nutrient and a disease or health-related condition to which the claim refers; (2) a copy of the statement upon which the claim is based; and (3) a balanced representation of the scientific literature relating to the nutrient level or nutrient-disease relationship to which the claim refers. 21 U.S.C. §§ 343(r)(2)(G)(ii); 343(r)(3)(C)(ii).

d. Should we require you to submit in a notification an analytical methodology for measuring the substance that is the subject of your submitted claim?

To impose such a requirement would exceed the parameters set forth in the statute, as stated directly above in response to item 3(c). Such a requirement would impose costs and delays that the statute aims to substantially reduce.

e. What is a balanced presentation [sic] of the scientific literature relating to the subject to which a claim refers that is required under section 403(r)(2)(G)(ii)(III) and (r)(3)(C)(ii)(III) of the act?

The statute refers to a "balanced representation," not a "balanced presentation." A balanced representation of the scientific literature is, by its ordinary meaning, a subset of the universe of all scientific literature concerning the claim that includes representative articles that favor and disfavor the claim.

f. Should FDA keep notifications confidential for 120 days after the date of their submission or should we place them in a public docket upon receipt?

Authoritative statements that form the basis for claims submitted under FDAMA Section 303 are public. Moreover, the public has a keen interest in ascertaining how FDA treats such claims. Accordingly, it would be inappropriate to hold the notifications containing the claims confidential. They should be placed in a public docket upon receipt.

g. If a notification is incomplete or does not support a claim, should we respond to it by letter or by issuing a regulation, and what should be the legal effect of letters were we to use them?

The answer to this question lies in the statute. If a claim is "incomplete," the statute provides for notification by the Secretary to the person making the claim that the person "has not submitted all the information required by" the statute. 21 U.S.C. §§ 343(r)(2)(G)(ii); 343(r)(3)(C)(ii). Therefore, consistent with the statute, if a submission is incomplete, the agency should serve the person making the submission with a letter identifying the precise reason why it has concluded that the submission is incomplete. Such an action would not constitute a final ruling on the submission because the person making the claim could provide the missing information needed to permit a substantive review. If, however, the FDA concludes that the notification does not "support" the

claim, or does not "support" the claim and is incomplete, those are rulings on the merits of the claim and should be the product of regulations promulgated pursuant to 21 U.S.C. §§ 343(r)(2)(H); 343(r)(3)(D).

Respectfully submitted,

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